§ 1.1

- REQUIREMENTS FOR NONTRANSPORTERS TO ESTABLISH AND MAINTAIN RECORDS TO IDENTIFY THE NONTRANSPORTER AND TRANSPORTER IMMEDIATE PREVIOUS SOURCES OF FOOD
- 1.337 What information must nontransporters establish and maintain to identify the nontransporter and transporter immediate previous sources of food?
- REQUIREMENTS FOR NONTRANSPORTERS TO ESTABLISH AND MAINTAIN RECORDS TO IDENTIFY THE NONTRANSPORTER AND TRANSPORTER IMMEDIATE SUBSEQUENT RECIPIENTS OF FOOD
- 1.345 What information must nontransporters establish and maintain to identify the nontransporter and transporter immediate subsequent recipients of food?

REQUIREMENTS FOR TRANSPORTERS TO ESTABLISH AND MAINTAIN RECORDS

1.352 What information must transporters establish and maintain?

GENERAL REQUIREMENTS

- 1.360 What are the record retention requirements?
- 1.361 What are the record availability requirements?
- 1.362 What records are excluded from this subpart?
- 1.363 What are the consequences of failing to establish or maintain records or make them available to FDA as required by this subpart?

COMPLIANCE DATES

1.368 What are the compliance dates for this subpart?

Subpart K—Administrative Detention of Food for Human or Animal Consumption

GENERAL PROVISIONS

- 1.377 What definitions apply to this subpart?
- 1.378 What criteria does FDA use to order a detention?
- 1.379 How long may FDA detain an article of food?
- 1.380 Where and under what conditions must the detained article of food be held?
- 1.381 May a detained article of food be delivered to another entity or transferred to another location?
- 1.382 What labeling or marking requirements apply to a detained article of food?
- 1.383 What expedited procedures apply when FDA initiates a seizure action against a detained perishable food?
- 1.384 When does a detention order terminate?

HOW DOES FDA ORDER A DETENTION?

- 1.391 Who approves a detention order?
- 1.392 Who receives a copy of the detention order?
- 1.393 What information must FDA include in the detention order?

WHAT IS THE APPEAL PROCESS FOR A DETENTION ORDER?

- 1.401 Who is entitled to appeal?
- 1.402 What are the requirements for submitting an appeal?
- 1.403 What requirements apply to an informal hearing?
- 1.404 Who serves as the presiding officer for an appeal, and for an informal hearing?
- 1.405 When does FDA have to issue a decision on an appeal?
- 1.406 How will FDA handle classified information in an informal hearing?

AUTHORITY: 15 U.S.C. 1333, 1453, 1454, 1455, 4402; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 332, 333, 334, 335a, 343, 350c, 350d, 352, 355, 360b, 362, 371, 374, 381, 382, 387, 387a, 387c, 393; 42 U.S.C. 216, 241, 243, 262, 264.

SOURCE: 42 FR 15553, Mar. 22, 1977, unless otherwise noted.

Subpart A—General Provisions

§1.1 General.

- (a) The provisions of regulations promulgated under the Federal Food, Drug, and Cosmetic Act with respect to the doing of any act shall be applicable also to the causing of such act to be done.
- (b) The definitions and interpretations of terms contained in sections 201 and 900 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 and 387) shall be applicable also to such terms when used in regulations promulgated under that act.
- (c) The definition of package in §1.20 and of principal display panel in §§ 101.1, 201.60, 501.1, 701.10 and 801.60 of this chapter; and the requirements pertaining to uniform location, lack of qualification, and separation of the net quantity declaration in §§ 101.105(f), 201.62(e), 501.105(f), 701.13(f) and 801.62(e) of this chapter to type size requirements for net quantity declaration in §§ 101.105(i), 201.62(h), 501.105(i), 701.13(i) and 801.62(h) of this chapter, to initial statement of ounces in the dual declaration of net quantity in §§101.105(j) and (m), 201.62(i) and (k), 501.105(j) and (m), 701.13(j) and (m) and 801.62(i) and

(k) of this chapter, to initial statement of inches in declaration of net quantity in §§ 201.62(m), 701.13(o) and 801.62(m) of this chapter, to initial statement of square inches in declaration of net quantity in §§ 201.62(n), 701.13(p) and 801.62(n) of this chapter, to prohibition of certain supplemental net quantity statements in §§ 101.105(o), 201.62(o), 501.105(o), 701.13(q) and 801.62(o) of this chapter, and to servings representations in §501.8 of this chapter are provided for solely by the Fair Packaging and Labeling Act. The other requirements of this part are issued under both the Fair Packaging and Labeling Act and the Federal Food, Drug, and Cosmetic Act, or by the latter act solely, and are not limited in their application by section 10 of the Fair Packaging and Labeling Act.

[42 FR 15553, Mar. 22, 1977, as amended at 58 FR 17085, Apr. 1, 1993; 75 FR 73953, Nov. 30, 2010; 78 FR 69543, Nov. 20, 2013]

§ 1.3 Definitions.

- (a) Labeling includes all written, printed, or graphic matter accompanying an article at any time while such article is in interstate commerce or held for sale after shipment or delivery in interstate commerce.
- (b) Label means any display of written, printed, or graphic matter on the immediate container of any article, or any such matter affixed to any consumer commodity or affixed to or appearing upon a package containing any consumer commodity.

§1.4 Authority citations.

- (a) For each part of its regulations, the Food and Drug Administration includes a centralized citation of all of the statutory provisions that provide authority for any regulation that is included in that part.
- (b) The agency may rely on any one or more of the authorities that are listed for a particular part in implementing or enforcing any section in that part.
- (c) All citations of authority in this chapter will list the applicable sections in the organic statute if the statute is the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, or the Fair Packaging and Labeling Act. References to an act or a section there-

of include references to amendments to that act or section. These citations will also list the corresponding United States Code (U.S.C.) sections. For example, a citation to section 701 of the Federal Food, Drug, and Cosmetic Act would be listed: Sec. 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371).

- (d) If the organic statute is one other than those specified in paragraph (c) of this section, the citations of authority in this chapter generally will list only the applicable U.S.C. sections. For example, a citation to section 552 of the Administrative Procedure Act would be listed: 5 U.S.C. 552. The agency may, where it determines that such measures are in the interest of clarity and public understanding, list the applicable sections in the organic statute and the corresponding U.S.C. section in the same manner set out in paragraph (c) of this section. References to an act or a section thereof include references to amendments to that act or section.
- (e) Where there is no U.S.C. provision, the agency will include a citation to the U.S. Statutes at Large. Citations to the U.S. Statutes at Large will refer to volume and page.
- (f) The authority citations will include a citation to executive delegations (i.e., Executive Orders), if any, necessary to link the statutory authority to the agency.

[54 FR 39630, Sept. 27, 1989]

Subpart B—General Labeling Requirements

§ 1.20 Presence of mandatory label information.

In the regulations specified in §1.1(c) of this chapter, the term package means any container or wrapping in which any food, drug, device, or cosmetic is enclosed for use in the delivery or display of such commodities to retail purchasers, but does not include:

- (a) Shipping containers or wrappings used solely for the transportation of any such commodity in bulk or in quantity to manufacturers, packers, processors, or wholesale or retail distributors:
- (b) Shipping containers or outer wrappings used by retailers to ship or